

Transmittal

PATENT COOPERATION TREATY

PCT

PCT Application  
PCT/CN2003/001145



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference IEC030035PCT		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CN03/01145	International filing date (day/month/year) 30. Dec. 2003 (30.12.2003)	Priority date (day/month/year) 31. Dec. 2002 (31.12.2002)	
International Patent Classification (IPC) or national classification and IPC IPC <sup>7</sup> C07C311/08, A61K31/18, A61K47/40, A61K47/48, A61P29/00			
Applicant INSITUTE OF RADIATION MEDICINE, ACADEMY OF MILITARY MEDICAL SCIENCES, PLA etc			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and /or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority ( see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty ,inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2)with regard to novelty ,inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input checked="" type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international opplication.</p>			

Date of submission of the demand 02. Aug. 2004 ( 02.08.2004)	Date of completion of this report 04. Jan. 2005 ( 04.01.2005)
Name and mailing address of the IPEA/CN 6 Xitucheng Rd., Jimen Bridge, Haidian District, 100088 Beijing, China Facsimile No. 86-10-62019451	Authorized officer Chen Mao Telephone No.86-10-62085572



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/CN03/01145

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

☐ the international application as originally filed☒ the description:

pages 1-12, as originally filed

pages, filed with the demand

pages, filed with the letter of

☒ the claims:

Nos 4-7,10, as originally file

Nos 1-3,8-9, as amended (together with any statement) under Article 19

Nos, filed with the demand

Nos, filed with the letter of

☒ the drawings:

sheets/fig 1-14, as originally filed

sheets/fig, filed with the demand

sheets/fig, filed with the letter of

☐ the sequence listing part of the description:

pages, as originally filed

pages, filed with the demand

pages, filed with the letter of

## 2. with regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☐ The amendments have resulted in the cancellation of:☐ the description, pages☐ the claims No.☐ the drawings, sheets/fig5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement:

Novelty (N)	Claims 2-7	YES
	Claims 1,8-10	NO
Inventive step (IS)	Claims	YES
	Claims 1-10	NO
Industrial applicability (IA)	Claims 1-10	YES
	Claims	NO

### 2. Citations and explanations (Rule 70.7)

#### Cited documents:

D1 US 3 840 597 A

D2 US 5 756 546 A

D1 disclosed a kind of substituted 2-phenyloxyalkyl sulfonamide compounds with anti-inflammatory activity and the pharmaceutical compositions thereof. When A does not exist in the formula (I) of claim 1, the compound of formula (I) is equal to "2-(4-methoxyphenoxy)-4-nitromethanesulfonamide" disclosed in D1 (see, example 14). When A exists, it is obvious to the skilled person in the art that the compounds of formula (I) have the same or similar anti-inflammatory activities as the compound in D1. Therefore, the subject matters of Claim 1, 8-10 are either lack of novelty or lack of inventive step and do not meet the requirements of PCT Art. 33(2) and (3).

Claim 2-3 each refers to the compound of formula (I) in which A is 4-methyl-cyclohexylamine, arginine or lysine. It was disclosed in D1 (see, column 3, line 1-31) that the compounds of the formula were acids when R was H, and could form salts with appropriate cation ions. The salts could be those of organic amines, such as methyl cyclohexylamine. In D2, it was taught that nimesulide-L-lysine salt has an improved solubility, and the improvement could be enhanced by the addition of L-arginine. There is no data in present application to show that the salts claimed in claim 2-3 have any unexpected effect. Claim 4-7 each refers to the mixtures, associated compounds, complexed compounds or inclusion compounds of formula (I) with povidone, phospholipid or cyclodextrin in the absence of A. As the povidone, phospholipid and cyclodextrin are the common assistants for improving solubility, it is obvious to the skilled in the art to combine them with the compound of formula (I) without any adverse effect. According to the above, Claim 2-7 are lack of inventive step, and do not meet the requirement of PCT Art. 33(3).

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## VI. Certain documents cited

## 1. Certain published documents (Rule 70.10)

<u>Application No.</u> Patent No.	<u>Publication date</u> (day/month/year)	<u>Filing date</u> (day/month/year)	<u>Priority date (valid claim)</u> (day/month/year)
US 5 756 546 A	26-05-1998	16-06-1995	16-06-1994
US 3 840 597 A	08-10-1974	03-07-1972	24-02-1971

## 2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure</u> (day/month/year)	<u>Date of written disclosure</u> <u>referring to non-written disclosure</u> (day/month/year)
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